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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,525	04/06/2000	Ralf M. Luche	200125.408	7819

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EXAMINER	
PROUTY, REBECCA E	
ART UNIT	PAPER NUMBER
1652	11

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/544,525	Luche
Examiner	**Art Unit**
Rebecca Prouty	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 23, 2002*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *45 and 46* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *45 and 46* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Claims 1-44 and 47-49 have been canceled. Claims 45-46 are at issue and are present for examination.

Applicant's election without traverse of Group XI, Claims 45 and 46 in Paper No. 8 is acknowledged.

The amendment filed 2/1/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation by reference of provisional application 60/142,338. While applicants response indicates that the recitation of the provisional application in the original transmittal contained a typographical error, there is no support in any of the original application papers for the corrected serial number (both references to this provisional recited the wrong serial number) and thus incorporation by reference of the subject matter of this application is new matter.

Applicant is required to cancel the new matter in the reply to this Office action.

The disclosure is objected to because of the following:

The description of the polypeptide of SEQ ID NO:2 and its substrate trapping mutants is confusing and inconsistent in several places within the specification. On page 7, lines 15-24

the specification describes substrate trapping mutants generated by replacing the aspartate at position 57 with an alanine residue or by replacing the cysteine at residue 88 with a serine. However residue 57 of SEQ ID NO:2 is not aspartate nor is residue 88 a cysteine. The correct aspartate and cysteine residues for producing a substrate trapping mutant of SEQ ID NO:2 appear to be at positions 39 and 71 based on page 7 lines 15-24 of applicants provisional application 60/128,225. (Note residues 57 and 88 appear to be the homologous residues for creation of substrate trapping mutants of the splice variant of SEQ ID NO:2 which is disclosed in provisional application 60/142,338). The incorrect amino acids for mutation are also recited on page 5, line 13. On page 12, lines 10-15 the specification states "The DSP-3 active site VHCLAGVSRS (SEQ ID NO:3) is encoded by nucleotide bases located at positions 258 through 285 of SEQ ID NO:1 (Fig. 1 start codon begins at nucleotide position number 1)" The next line goes on to state that DSP-3 as provided in Figure 1 is 184 amino acids in length encoded by 552 base pairs. Inspection of the nucleotide sequence of Figure 1 (SEQ ID NO:1) and its translation in Figure 2 (SEQ ID NO:2) shows that many features of these sequences are described incorrectly in the specification. SEQ ID NO:1 is 875 bases long and encodes a protein (SEQ ID NO:2) of 167 amino acids in length. The sequence encoding the active site

sequence VHCLAGVSRS is found at bases 287-317 of SEQ ID NO:1 and the start codon of SEQ ID NO:2 is encoded by nucleotides 84-86 of SEQ ID NO:1. Page 44 lines 25-30 repeats many of these incorrect characterizations of SEQ ID NOS: 1 and 2.

Appropriate correction is required.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 46 recites substrate trapping mutants of SEQ ID NO:2 with a substitution at position 57 or 88 of SEQ ID NO:2. However, for the reasons discussed above in the objection to the specification, substitutions of amino acids 57 or 88 of SEQ ID NO:2 are unlikely to in fact be substrate trapping mutations.

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for substrate trapping mutations of amino acids 39 and 71 of SEQ ID NO:2, does not reasonably provide enablement for any substrate trapping mutant of any dual specificity phosphatase having 50% identity to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make the invention commensurate in scope with these claims.

Claim 45 is so broad as to encompass any substrate trapping mutant of any dual specificity phosphatase having 50% identity to SEQ ID NO:2. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of substrate trapping mutants broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and amino acid sequence of a single dual specificity phosphatase and 2 specific substrate trapping mutations thereof.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid

modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all substrate trapping mutants of any dual specificity phosphatase with 50% identity to SEQ ID NO:2 because the specification does **not** establish: (A) regions of the protein structure which may be modified to reduce phosphatase activity without effecting substrate binding activity; (B) the general tolerance of dual specificity phosphatases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues of SEQ ID NO:2 with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the

claimed invention in a manner reasonably correlated with the scope of the claims broadly including any substrate trapping mutant of any dual specificity phosphatase having 50% identity to SEQ ID NO:2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of substrate trapping mutants having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty
Primary Examiner
Art Unit 1652